510(K) SUMMARY

INTEGRA® Wound Matrix (Thin)

Submitter's name and address:

Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536 USA

Contact person and telephone number:

Stephen Beier
Specialist, Regulatory Affairs
Telephone: 609.936.5436
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Date Summary was prepared:

January 11, 2012

Name of the device:

Proprietary Name:	INTEGRA® Wound Matrix (Thin)
Common Name:	Collagen Wound Dressing
Classification Name:	Not Classified
Product Code:	KGN

Substantial Equivalence:

INTEGRA® Wound Matrix (Thin) is substantially equivalent in function and intended use to the predicate device detailed in the following table.

510(k) Number	Product Code	Trade Name	Manufacturer
K022127	KGN	INTEGRA® Matrix Wound Dressing	Integra LifeSciences Corporation

Device Description:

INTEGRA® Wound Matrix (Thin) is a collagen-glycosaminoglycan wound dressing that maintains and supports a healing environment for wound management. INTEGRA® Wound Matrix (Thin) is supplied sterile and is intended for one-time use. The device is provided in a thinner form than the predicate, K022127.

Intended Use:

INTEGRA® Wound Matrix (Thin) is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds. The device is intended for one-time use.

Substantial Equivalence Comparison:

INTEGRA® Wound Matrix (Thin) has the same design, materials, and chemical composition as the predicate device (K022127). The only difference between the two products will be the device thickness. All technological characteristics (i.e. pore size, collagen-nativity, extent of collagen

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cross-linking, and glycosaminoglycan content) are the same for INTEGRA® Wound Matrix (Thin) and the predicate device.

Testing and Test Results:
INTEGRA® Wound Matrix (Thin) and INTEGRA® Matrix Wound Dressing (K022127) are comprised of identical materials and are sterilized by identical methods.

All test results were acceptable. In addition to biocompatibility testing, the product is tested to meet the following performance characteristics: pore size, collagen nativity-FTIR test of denaturing, chondroitin-6-sulfate content, and degree of cross-linking. Furthermore, the history of clinical use of similar collagen products, including the predicate device, manufactured and marketed by Integra LifeSciences Corporation has been cited in this 510(k) Premarket Notification.

Conclusion:
The modified INTEGRA® Wound Matrix (Thin) is substantially equivalent to the commercially marketed device, INTEGRA® Matrix Wound Dressing (K022127).

The modifications expressed in this 510(k) Premarket Notification do not change the intended use or fundamental scientific technology of the device, and do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Integra LifeSciences Corporation
% Mr. Stephen Beier
Specialist, Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

FEB - 9 2012

Re: K113104
Trade/Device Name: INTEGRA® Wound Matrix (Thin)
Regulation Name: Unclassified
Product Code: KGN
Dated: January 11, 2012
Received: January 12, 2012

Dear Mr. Beier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: INTEGRA™ Wound Matrix (Thin)

Indications For Use: INTEGRA™ Wound Matrix (Thin) is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds. The device is intended for one-time use.

Prescription Use _X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113104